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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,641	02/22/2002	Patrick A. Haverkost	BSI-486US	2371

7590 10/29/2007  
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EXAMINER
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DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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10/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/081,641

Applicant(s)

HAVERKOST ET AL.

Examiner

Glenn K. Dawson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-33,47,48,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-16,18-29,48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,10,11,30-33,47,51 is/are rejected.
- 7) ☒ Claim(s) 7,8 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-6,10,11,30 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Cornelius, et al.-6068634.

Cornelius discloses a stent introducer having a shaft 18 with a distal tip 28, an inner sheath 16 over the shaft, a stent 20 over the inner sheath, an anterograde sheath 24 attached proximally to the tip and mounted over a portion of the stent, and anchoring means 14 for anchoring the stent's proximal end after the stent has been released and expanded and which minimizes axial movement of the proximal end of the stent relative to the body lumen. The sheath is comprised of tube 16 and balloon 14. Therefore, the stent is mounted concentrically over the inner sheath. The balloon if slightly expanded before the tip were moved distally to release the distal end of the stent could anchor the proximal end of the stent against axial movement, the balloon could also be used to set the stent against and into the vessel wall if inflated to a high enough pressure. The inner sheath defines the inflation lumen for the balloon. The balloon is mounted concentrically under the stent. A retrograde sheath 22 extends distally over the balloon. A spacer 27 is between the inner sheath and the anterograde sheath. For claim 47, the examiner contends that the two sleeve portions do define a lumen therethrough as theoretical extensions between the two sleeves would bound the lumen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-33,47 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornelius, et al.-634 in view of Heyn-5201757 and Fiedler-6056759.

Cornelius discloses the invention as claimed with the exception of the length of the sheaths. Heyn and Fielder disclose oppositely slidable sheaths covering a stent, the ends of the sheaths can either abut or overlap. It would have been obvious to have provided the sheaths of Cornelius to entirely cover the stent and either abut or overlap (which would then unequivocally form a lumen therethrough) in order to completely protect the entire stent before deployment. Making one of the sheaths longer would be a mere obvious design choice and would not affect the manner of use at all.

***Allowable Subject Matter***

Claims 7,8 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 08-15-2007 have been fully considered but they are not persuasive.


As pointed out above, either the two sleeves already "define" a lumen therethrough, or when the combination is made and the two sleeves either abut or overlap, a lumen therethrough is certainly defined therethrough. The sheath is formed by the tube and the balloon as they are in essence integral. In this interpretation, the stent is indeed surrounded concentrically by the sheath.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd E. Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
20 October 2007